

## REMARKS

### **I. Status of the Application**

Claims 1-6 and 8-16 are pending in the application. Applicants gratefully acknowledge the Examiner's withdrawal of the rejection of claims 1, 2 and 5-11 under 35 U.S.C. §112, first paragraph and of claims 1-14 under 35 U.S.C. §103(a) as being unpatentable over McGinity et al. in view of Subramaniam et al., and further in view of Goedemoed et al. Claims 1 and 6 stand rejected under the judicially created doctrine of obviousness-type double patenting over U.S. Patent No. 6,685,957. Claims 1-6 and 8-16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Vacanti et al., U.S. Patent No. 6,348,069, in view of Martin et al., U.S. Patent No. 6,162,537.

Applicants respectfully request entry and consideration of the foregoing remarks, which are intended to place this case in condition for allowance.

### **II. Formal Matters**

At page 3, paragraph 2 of the instant Office Action, claims 1 and 6 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6 and 7 of U.S. patent No. 6,685,957. The Examiner is of the opinion that although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the instant application, like the claims in the '957 patent, are drawn toward a process for preparing an implant for the controlled release and delivery of bioactive agent, and both processes comprise a wet spinning technique.

In response, Applicants submit herewith a Terminal Disclaimer to obviate the Examiner's double patenting rejection of claims 1 and 6 as being unpatentable over claims 1, 6 and 7 of U.S.

Patent No. 6,685,957. Applicants respectfully submit that the Terminal Disclaimer renders the obviousness-type double patenting rejection moot and that claims 1 and 6 are allowable.

Applicants submitted an Information Disclosure Statement and a Form 1449 on October 28, 2003 in the instant application. Applicants note that they have not received a copy of the Form 1449 signed by the Examiner indicating that he has considered the references cited therein. Applicants respectfully request such a copy.

**III. Claims 1, 15 and 16 Are Nonobvious over Vacanti et al. in view of Martin et al.**

At page 3, paragraph 4 of the instant Office Action, claims 1-6 and 8-16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Vacanti et al., U.S. Patent No. 6,348,069, in view of Martin et al., U.S. Patent No. 6,162,537. The Examiner is of the opinion that one of ordinary skill would be motivated to prepare polymer fibers using a wet spinning technique and incorporate therein active agents for implantation into specific tissue sites. One of ordinary skill would expect the beneficial effect of the drug when released into the sites. The Examiner concludes, therefore, that the invention as a whole would have been *prima facie* obvious to one of ordinary skill at the time it was made.

Applicants respectfully traverse this rejection. Applicants respectfully submit that to establish *prima facie* obviousness of a claimed invention, each and every claim limitation must be taught or suggested by the prior art. The cited references, alone or in combination, fail to teach or suggest each and every element of the claimed invention. The pending claims are directed to a process for preparing an implant for controlled release of a bioactive agent *in vivo* comprising a polymer fiber loaded with one or more bioactive agents, said process comprising a wet spinning technique having the steps of providing a polymer, a first solvent and a second

solvent, wherein the polymer is soluble in the first solvent and insoluble in the second solvent, and wherein the first solvent is miscible with the second solvent and immiscible with water, providing a solution of the polymer in the first solvent, *adding an aqueous solution of the bioactive agent to the polymer solution to form an emulsion*, immersing the emulsion in the second solvent by injecting the emulsion through a nozzle into the second solvent, allowing the first solvent to migrate into the second solvent to form a solid polymer fiber loaded with the bioactive agent, and shaping the polymer fiber into an implant.

Applicants' novel method, which includes the step of forming an emulsion, beneficially effects the formation of polymer fibers (specification, page 3, line 32). Applicants' claimed process produces polymers wherein the bioactive materials are an integrated part of the polymer fiber (specification, page 2, lines 8-10). The claimed process provides one of skill in the art the ability to homogenously distribute bioactive agents into polymers, as well as the ability to use mild conditions, thus allowing the production of polymer fibers containing, for example, heat or chemical labile biomaterials (page 2, lines 29-22).

The cited references fail to teach or suggest each and every element of the claimed invention. Vacanti et al. is directed to fibrous or polymeric matrices (column 2, lines 66-67) that may include bioactive agents (column 5, lines 45-49). Vacanti et al. neither teaches nor suggests a wet spinning technique, as claimed by Applicants. Indeed, the Examiner acknowledges that Vacanti et al. does not disclose a wet spinning technique (page 4, paragraph 1 of the instant Office Action). Furthermore, Vacanti et al. neither teaches nor suggests Applicants' claimed step of *adding an aqueous solution of the bioactive agent* to the polymer solution to *form an emulsion*. Accordingly, Vacanti et al. fails to teach or suggest the claimed invention.

Martin et al. fails to cure the deficiencies of Vacanti et al. Martin et al. is directed to bicomponent fibers made using wet spinning, melt spinning and solution dry spinning processes (column 4, lines 1-9). The wet spinning process of Martin et al. includes dissolving polymer in solvent followed by extruding the solvent polymer mixture into a coagulation mixture such that polymer fibers are formed (column 10, lines 39-56). Martin et al. neither teaches nor suggests Applicants' claimed step of *adding an aqueous solution of the bioactive agent* to the polymer solution to *form an emulsion*. Although Martin et al. states that pharmaceutically active agents may be added to the fibers, the reference provides no teaching or suggestion that it is desirable or even possible to add pharmaceutically active agents to the polymer solution in an emulsion step.

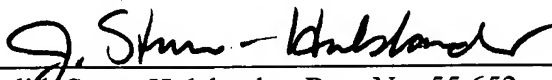
Thus, the combination of references fails to teach each and every element of the claimed invention. Accordingly, Applicants respectfully request that rejection of claims 1-6 and 8-14 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

#### IV. Conclusion

Having addressed all outstanding issues, Applicants respectfully request reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

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